UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/236,468	01/25/99	SOPPET	D PF201D1

HM12/1128

JAMES H. DAVIS, ESQ.
HUMAN GENOME SCIENCES, INC.
9410 KEY WEST AVENUE
ROCKVILLE MD 20850

EXAMINER	
SPECTOR, L	
ART UNIT	**PAPER NUMBER**
1647	13

DATE MAILED: 11/28/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 9/1/00.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 21-76 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 21-27, 70-75 is/are allowed.

☒ Claim(s) 28-69, 76 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6 & 9

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948 (Substitute)

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

★ U.S. GPO: 1996-409-290/40029

Part III: Detailed Office Action

Notice: **Effective June 18, 2000**, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit **1647**.

Information Disclosure Statement:

The information disclosure statements filed 1/27/00 and 9/1/00, papers numbered 6 and 9, respectively, have been considered. References C7-C9 could not be considered, as no copies could be found of those sequences. Reference C6, however, was considered, as it came to the examiner's attention in the review of the PTO sequence search results.

Restriction Requirement:

Applicant's election with traverse of Group II, corresponding to newly introduced claims 21-76 in Paper No. 10 filed 9/1/00 is acknowledged. The traversal is on the ground(s) that (1)the groups of inventions are not independent, and (2) the examination of the entire application would not constitute a burden to search. This is not found persuasive because with respect to point (1) above, the inventions are distinct as noted in the last Office Action, as shown by the distinctness described therein. Applicant's attention is directed to MPEP 806.05. With respect to point (2) above, contrary to applicants' assertion that any search of the prior art in regard to the claimed proteins will reveal whether any prior art exists as to the other Groups, a search is directed to references which would render the invention obvious, as well as references directed to anticipation of the invention, and therefore requires a search of relevant literature in many different areas of subject matter. For example, it is not uncommon that an antibody to a protein exists and is known prior to the isolation of the protein itself, such that the search for the antibody is not coextensive with the search for the protein.

The requirement is still deemed proper and is therefore made FINAL.

Objections and Rejections under 35 U.S.C. §112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 51-69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims are directed to specific fragments of the protein of SEQ ID NO: 2. Applicants, in paper number 10, point to page 6 lines 28-31 and page 32, lines 10-12 for basis for the new claims. However, the Examiner finds that the former portion of the specification is directed to is merely a portion of the description of Figure 2, which states that the figure shows which regions would be expected to be extracellular or intracellular, and that the antigenic index corresponds to the hydrophilicity (extracellular) plot. The latter portion merely states that the disclosed polypeptide, fragments, and derivatives thereof may be used for the production of antibodies. There is no conception in the specification as originally filed of the specific fragments which applicants now seek to claim. The generic disclosure of antigenic portions of the protein, with no reference to particular regions as now claimed, coupled with a wish to make antibodies to such is insufficient to support the newly submitted claims.

Claims 29-36 and 44-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The enablement of claim(s) 29-36 and 44-50 requires availability of the specific sequences as contained in the deposited plasmid claimed therein. This determination has been made because said

plasmid is not fully disclosed nor has it been shown to be publicly known and freely available. Accordingly, it is deemed that a deposit of plasmids containing these sequences should have been made in accordance with MPEP Chapter 2400 and 37 C.F.R.§§1.801-1.809.

The Examiner acknowledges the deposit of organisms under accession numbers ATCC 97186 under terms of the Budapest Treaty on International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure in compliance with this requirement. Applicant is advised that the Patent Office accepts Budapest approved deposits, as long as assurance is provided that the deposited material will be made irrevocably available with no restrictions upon issuance of a patent. See MPEP Chapter 2400.

Claims 37-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a protein having at least 90% identity to either SEQ ID NO: 2 or the protein encoded by the deposited plasmid (once the deposit has been perfected, see above), which protein either retains activity as a PTH receptor or binding protein or alternatively does not include novel epitopes not found in the protein of SEQ ID NO: 2 or that encoded by the deposited plasmid, does not reasonably provide enablement for proteins which do not retain the binding function of the disclosed protein and which include epitopes not native to the disclosed protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification discloses as uses for the claimed protein that the protein is a PTH receptor, and that the protein may additionally be used for the production of antibodies to such.

Polypeptides which are only 90% identical to SEQ ID NO: 2 are structurally and may be functionally distinct from the polypeptide having SEQ ID NO: 2. It is not predictable as to what functional properties these polypeptides will possess. In fact, it is not predictable that they can be used as G-protein coupled PTH receptors. While enablement would reasonably be found to be commensurate in scope with species 90% identical to SEQ ID NO: 2 and which retain PTH receptor function, the specification does not teach how to use those species which do not retain that function,

other than for the production of antibodies.

With respect to the use of the protein to make antibodies, only those species which do not include epitopes not native to the disclosed protein are adequately described and enabled. It is not predictable what changes would disrupt epitopes or alternatively introduce novel epitopes. The protein is useful for the production of antibodies only insofar as those antibodies are reactive with the disclosed protein, that having SEQ ID NO: 2. With respect to any epitopes which do not occur in SEQ ID NO: 2, there is no written description of proteins having such epitopes. The prior art does not recognize predictability in determining epitopes. The specification contains no guidance as to which species having 90% identity to SEQ ID NO: 2 would be useful for the generation of antibodies reactive with the protein of SEQ ID NO: 2, and there are no working examples of such. Therefore, the Examiner concludes both that the written description is not supportive of species 90% identical to SEQ ID NO: 2 which can be used to make antibodies specific to the protein of SEQ ID NO: 2, and also that the specification as originally filed does not provide adequate guidance to allow the person of ordinary skill in the art to practice the claimed invention in a manner commensurate in scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28 and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28 and 76 are drafted in product-by-process format, but fail to recite sufficient details of the process. For example, the claims recite 'culturing a host cell' without any specification of what the host cell is or may or may not have been transformed or transfected with. Amendment to recite that the host cell comprises a heterologous nucleic acid encoding the protein of claim 21 (or 70, as

appropriate) would be remedial.

Prior Art:

The claims are free of the prior art.

Usdin et al., JBC 270:15455, cited by applicants, discloses a protein 99% identical to SEQ ID NO: 2 and identifies such as the PTH2 receptor. This publication post dates the effective filing date of the instant application by 24 days.

Claims 21-27 and 70-75 are allowable.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 8:00 A.M. to 4:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 305-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. **Please** advise the Examiner at the telephone number above when an informal fax is being transmitted.

Lorraine Spector, Ph.D.
Primary Examiner

LMS
09/236468.1
11/27/00